UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Biomedical Device Consultants & Laboratories of Colorado, LLC,

Plaintiff,

v.

TA Instruments – Waters, LLC,

Defendants.

Civil File No. 0:17-cv-03403

DECLARATION OF MICHAEL GIRARD IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

I, Michael J. Girard, hereby declare and state as follows:

1. I have been retained by Plaintiff Biomedical Device Consultants & Laboratories of Colorado, LLC ("BDC") to offer technical analysis and opinions regarding various issues relevant to this action, including infringement and validity of the Patents-in-Suit, U.S. Patent Nos. 8,584,538 ("the '538 Patent"), 8,627,708 ("the '708 Patent"), 9,186,224 ("the '224 Patent"), 9,237,935 ("the '935 Patent") (collectively, the "Patents-in-Suit"). I have personal knowledge of the facts herein, and if called as a witness, I could and would testify competently thereto.

2. My education includes a Bachelor of Science in Civil (Structural) Engineering from the University of Illinois, and a Master of Business Administration from the University of St. Thomas.

3. I am currently the President of my own consulting firm, Girard Technical Services, Inc. My firm provides research and development, engineering, and technical management consulting services in the medical device industry.

4. I have thirty-seven years of experience in engineering, twenty-seven of which are in the medical device industry. I am a named inventor on 38 issued U.S. Patents with additional applications pending.

5. My experience includes work with many cardiovascular devices and specifically includes 19 years of heart valve experience. I've worked for several medical device companies in the role of development and testing of both surgical and transcatheter delivered prosthetic heart valves. Testing of heart valves usually includes durability testing at accelerated rates with equipment like the systems produced by BDC and TA Instruments. Therefore, I am very familiar with durability test equipment and the requirements of such testing. My curriculum vitae is attached hereto as Exhibit A.

A. Technology Overview

6. This case concerns equipment used for durability or high cycle fatigue testing of heart valves. Before any medical device, such as a heart valve, is marketed it must meet certain regulatory standards. International bodies, such as the International Organization for Standardization ("ISO"), set certain standards, such as those for testing the durability of medical devices, including heart valves. The specific standards for heart valves are defined in ISO 5840.

7. Prosthetic heart valves must be tested to ensure that they will function for the anticipated life of the patient by opening and closing the valve leaflets under flows and pressures that are present within the human vascular system. The normal human heart beats about 40 million times each year. The test requirements for evaluating prosthetic heart valves according to the standards require that the valves be able to

survive and function for hundreds of millions of cycles (e.g., at least 5 years or 200 million cycles). The valves must also be able operate over a specific range of opening and closing pressures that simulate physiological conditions, and therefore testing standards require that a specific pressure differential be generated across the valve when closed.

8. Testing systems use a test fluid to mimic blood and pressurize the fluid to mimic the blood pressure in the human body. Testing requires fluid flow through the valve and creating a pressure differential across the test valve when closed at a certain minimum pressure for a certain length of the cycle. A "drive mechanism" such as a pump drives the test fluid into the test chamber in order to create the fluid flow and desired pressure conditions. In order to complete hundreds of millions of cycles in a commercially viable timeframe, durability testing is done on an "accelerated" basis. In other words, the speed of the cycles is faster than a normal human heartbeat (a normal beat rate is 70 beats per minute - bpm). Using current technology at accelerated cycling of 800 bpm, testing takes approximately six months to simulate 200 million cycles.

B. Problems in Prior Art Technology

9. The Patents-in-Suit identify several problems with the prior art.

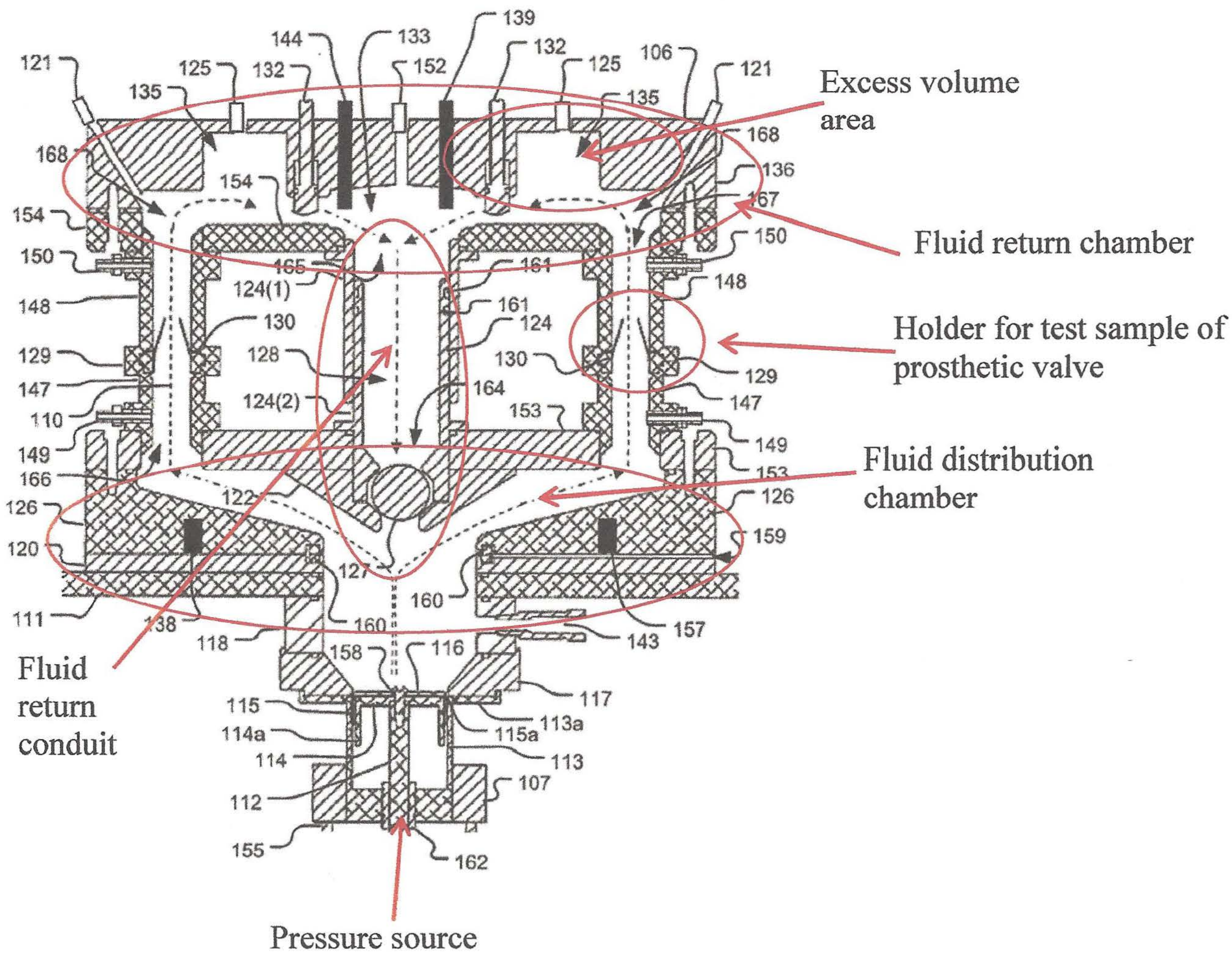
10. Driving mechanisms in the prior art had limited control over closing rates and would often produce "pressure spikes" when the systems maintain pressure above the testing threshold for the amount of time required by testing standards. These pressure spikes are undesirable because they wear out valves during testing faster than they would be worn out in the human body, causing false test failures.

11. According to the Patents-in-Suit, prior art valve testing devices also experienced operational problem. For example, one prior art device used a flexible metallic bellows to pressurize. '538 Patent col.1 ll.34-36. However, a higher load is required to drive the metallic bellows and can thus, impact the reliability of the test system and increase maintenance requirements which increases the already lengthy durability testing process.

C. Overview of the Patents-in-Suit

12. The Patents-in-Suit propose to solve these problems in the prior art.

13. For example, the '935 Patent covers a device for accelerated testing of valved prosthetics with several components including a test chamber and an "excess volume area" that is connected to a return chamber. The excess volume area and return chamber within the test chamber are shown below:



14. Another patent, the '224 Patent, covers a method for operating a test system with an excess volume area. The '224 Patent describes a method that includes storing a volume of the test fluid (which approximates blood) in an "excess volume area" when the system is in a "drive" stroke of the system that opens the prosthetic valve and releases the fluid from the area during the "return" stroke of the system.

15. The excess volume area improves the testing environment by minimizing unnatural and undesirable pressure spikes and provides advantages of speed and longevity in the drive system. When the system is driving test fluid through the

prosthetic valve, the excess volume area is able to store the excess volume downstream of the prosthetic test valve. This can alleviate some of the system pressure during the drive stroke. The excess volume area also provides compliance that controls the resistance and the forward flow pressure gradients across the valve, and minimizes unnatural and undesirable pressure noise or spikes. During the reverse stroke of the motor when the valve is closing, the excess volume area and compliance helps to build back pressure on the valve, return the downstream volume to the pump and minimize unnatural and undesirable valve closing pressure spikes, i.e., recoil, that can negatively impact the durability of the prosthetic test valve.

16. The Patents-in-Suit offer potential advantages for heart valve durability testing compared to the prior art. The use of the excess volume area and the avoidance of pressure spikes allows the system to better comply with the rigors of the durability testing standards without exposing the test valves to undesirable, excess, and clinically irrelevant pressures.

D. Infringement Analysis of DuraPulse Test System

17. I understand that the accused device in this case is the DuraPulse Heart Valve Test Instrument ("DuraPulse"). To understand the components of the DuraPulse and their operation, I have reviewed the following: the TA Instruments website offering the DuraPulse for sale, the sales brochure for the DuraPulse attached to the Complaint in this case, pictures of the DuraPulse included in BDC's motion for preliminary injunction, a video of the operation of the DuraPulse available at https://www.youtube.com/watch?v=KgmpQCRrYpQ, and U.S. Patent No. 9,662,210

("the '210 Patent"), attached hereto as Exhibit B. The '210 Patent belongs to Defendant TA Instruments-Waters, LLC ("TA Instruments"). The '210 Patent is entitled "System for Testing Valves" and, based on the diagrams and description, appears to describe the DuraPulse. In addition, I understand that BDC's CEO Dr. Craig Weinberg has observed the DuraPulse and the '210 Patent describes that product.

18. I understand that the patent infringement analysis involves two steps: (1) claim construction, and (2) comparison of the accused product to the construed claims. I understand that direct infringement of an apparatus claim requires that each and every limitation set forth in a claim appear in the accused products. I further understand that direct infringement of a method claim requires all steps of the claimed method to be performed by or attributable to a single entity.

i. Claim Construction

19. I understand that claim terms are to be given the ordinary and customary meaning of the term as evaluated from the perspective of one of ordinary skill in the art at the time of the invention. I further understand that the claim term is to be read in context of the claim itself and in the context of the entire patent, including the specification, but that limitations from the specification should not be read into the claims.

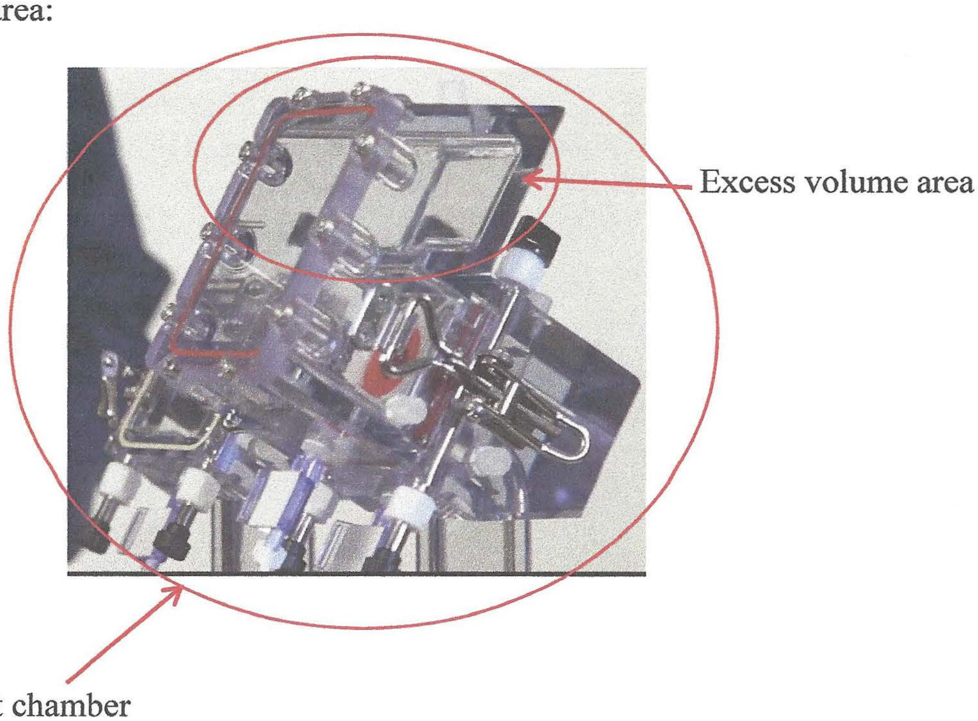
20. Based on context, including both the claims and the specification, the person of ordinary skill would understand that the term "compliance chamber" to mean "a cavity or volume that functions to absorb some of the pressure in the system." This is explained directly in the specification of the Patents-in-Suit. *See, e.g.*, '538 Patent col.8 ll.59-62. The specification explains that the chamber or chambers absorb some of the

pressure placed upon the fluid in the test chamber and can also impact the recoil. Likewise, the compliance chamber minimizes the effect of rapidly changing pressure gradients associated with accelerated testing. Finally, the compliance chamber is "a cavity or volume" because the specification notes that it may be air or another gas and may directly contact the fluid or may be separated from the fluid by a membrane.

ii. Comparison of Claim Elements to DuraPulse

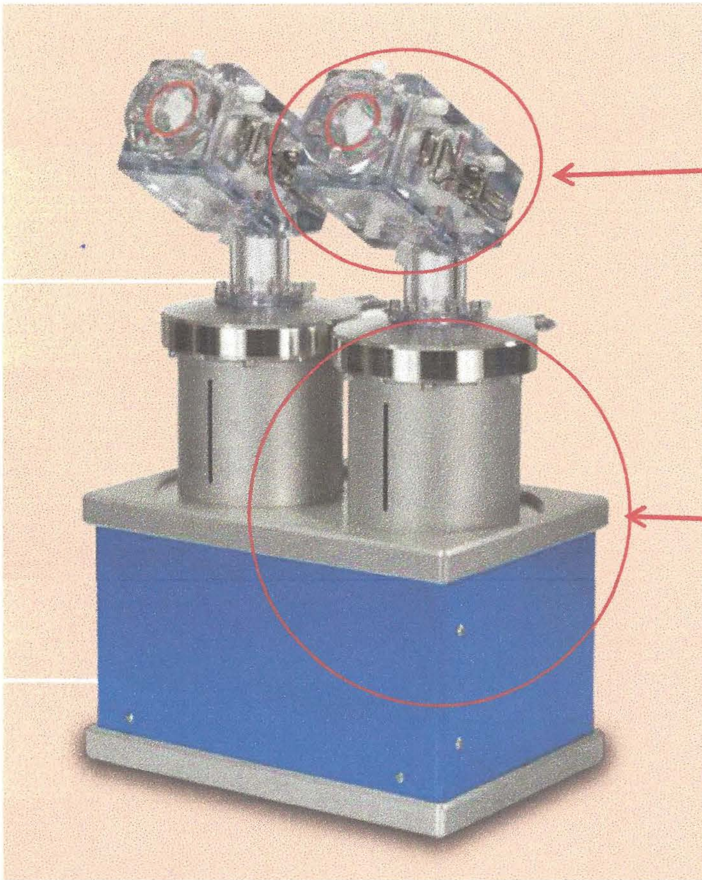
21. It is my opinion that the DuraPulse infringes at least claims 1 and 9 of the '935 Patent. In addition, it is my opinion that use of the DuraPulse infringes at least claims 1 and 6 of the '224 Patent.

22. The DuraPulse includes all the elements of the Patents-in-Suit. For example, an image of the DuraPulse is shown below, as noted it has a test chamber with an excess volume area:



23. The DuraPulse also has a drive motor that operates the system at an

accelerated rate:



[A] Pressurizable test chamber

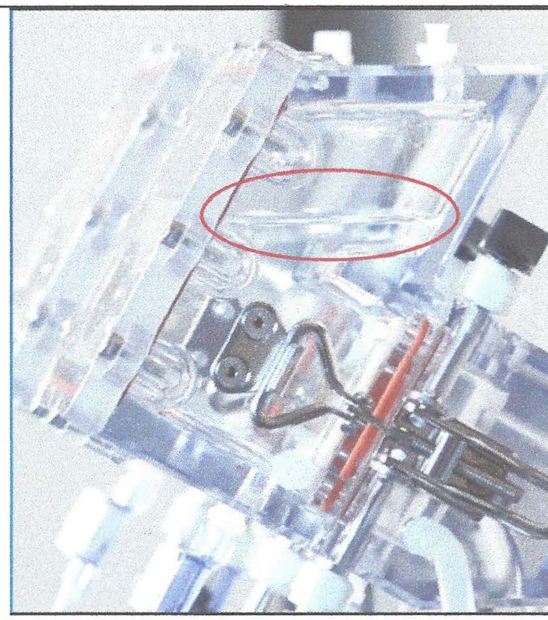
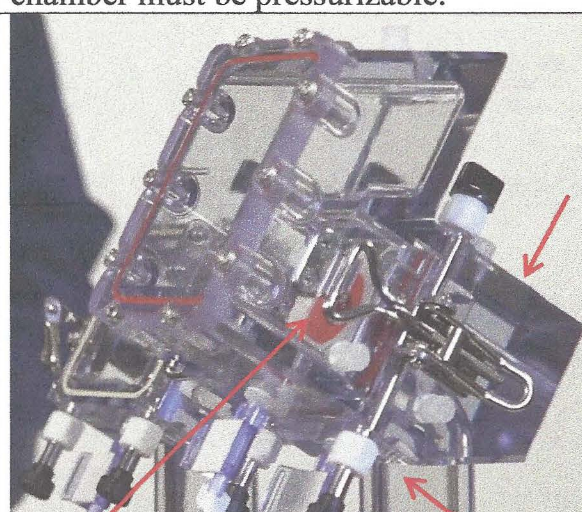
[B] Drive motor that is a pressure source and operates at 900-1800 beats per minute

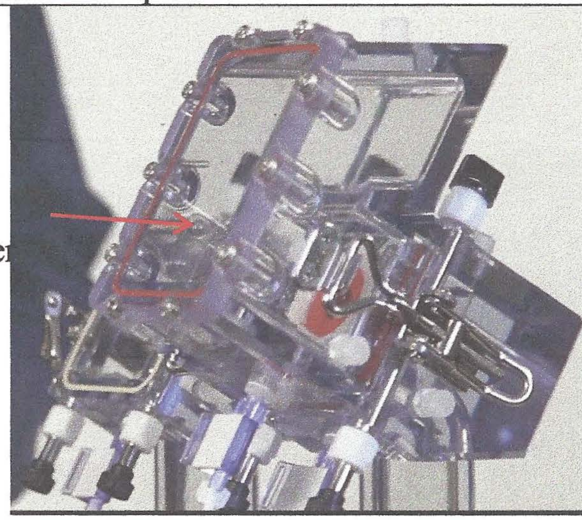
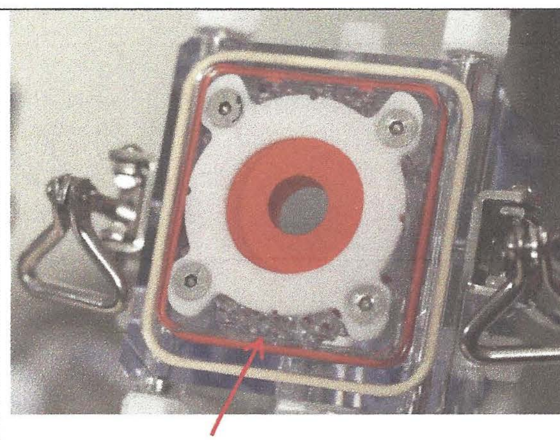
24. As explained in the following claim charts, it is my opinion that due to these features, and the other features discussed in the charts, that the DuraPulse infringes claims of the Patents-in-Suit.

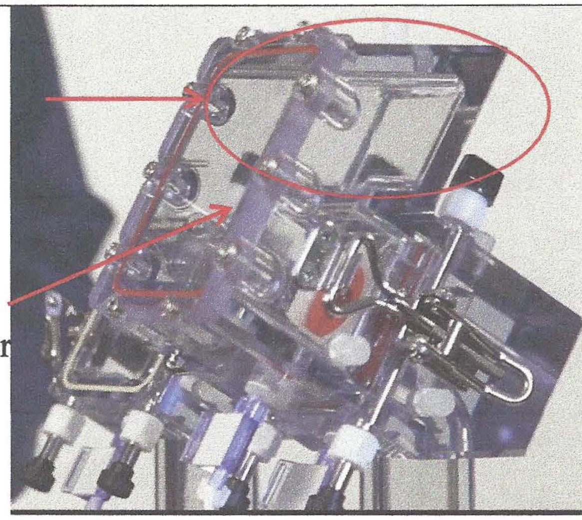
25. The '935 Patent:

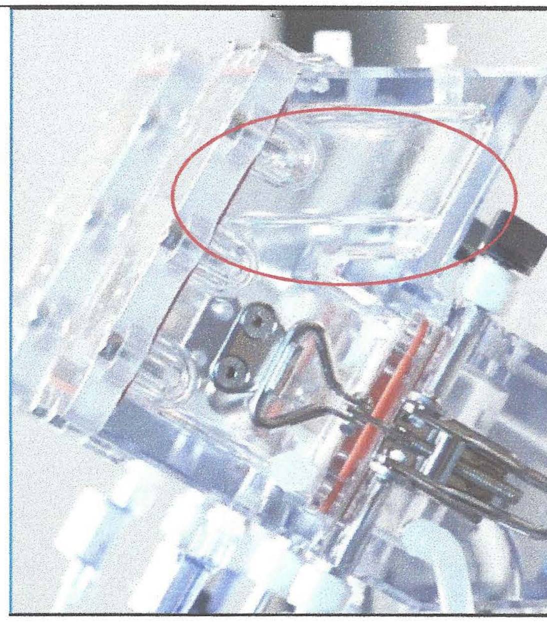
Claim Limitation	Claim Construction	Presence of Limitation in DuraPulse System
1. A device for accelerated cyclic testing of a valved prosthetic device comprising		The DuraPulse product is advertised by TA Instruments as a "Heart Valve Test Instrument." http://www.tainstruments.com/heart-valve-durability-test-instrument/. A prosthetic heart valve is a valved prosthetic device.

		The DuraPulse product is also touted by TA Instruments as a device "for *accelerated* heart valve durability testing." http://www.tainstruments.com/heart-valve-durability-test-instrument/ (description tab, emphasis added). TA Instruments notes that it can be run at over 30Hz, which is well above the normal human heart rate. Further, the TA Instruments website states that the DuraPulse "provides testing to the ISO 5840 standard for heart valve durability assessment." This standard requires cyclic testing. Therefore, the DuraPulse is a system for "accelerated cyclic testing of a valved prosthetic device."
a pressure source configured to drive a test system fluid cyclically within the device above a normal physiological rate, at an accelerated pulsed rate of greater than 200 beats per minute within the device; and		 The DuraPulse device is shown above. It includes a pressure source (contained in the base/cylinders in the above image). The device operates at a frequency of 15-30+ Hz. *See* http://www.tainstruments.com/wp-content/uploads/TA_Heart_Valve_Tester.pdf at 3. Hertz (Hz) is a unit of measurement for cycles per second. Therefore, mathematically, 15-30 Hz frequency corresponds to a rate of 900-1800 beats per minute for the test system fluid within the device.

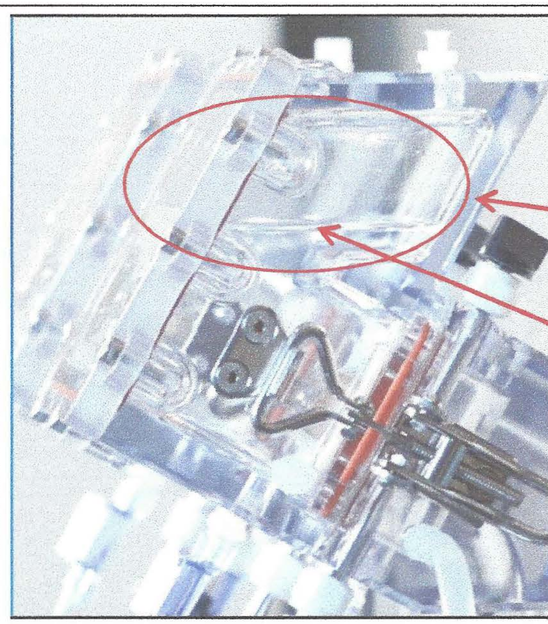
a pressurizable test chamber for containing the test system fluid and further comprising		 The above image shows the DuraPulse test chamber. The red circle depicts the fluid line, showing that the test chamber contains test system fluid. In order for the DuraPulse to function as a heart valve testing system, the test chamber must be pressurizable.
a fluid distribution chamber positioned on a first side of the valved prosthetic device and in fluid communication with the pressure source;	Test sample holder for prosthetic heart valve	 Fluid Distribution Chamber Cylinder The above picture of the DuraPulse device shows a fluid distribution chamber positioned on one side of the prosthetic heart valve being tested. The clear cylinder below the fluid distribution chamber provides fluid

		communication between the fluid distribution chamber and the pressure source.
a fluid return chamber positioned on a second side of the valved prosthetic device;		Fluid Return Chambe  On the other side of the prosthetic heart valve (the side opposite the fluid distribution chamber), is a fluid return chamber, shown with the red arrow.
a fluid return conduit both structurally and fluidly connecting the fluid distribution chamber to the fluid return chamber; and		 Small channels, one of which is marked with a red arrow, surround the test sample holder. The '210 Patent refers to these as "return flow orifices." '210 Patent col.9 ll.49-53 & fig.6b. The video of the operation of the DuraPulse confirms that these channels are in the system and allow return flow of test fluid between the fluid return chamber and fluid distribution chamber.

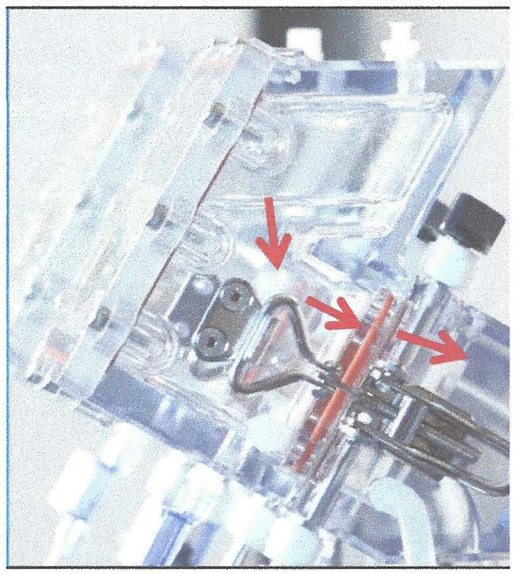
		These conduits allow test fluid to move from the fluid return chamber back to the fluid distribution chamber. In other words, the conduits "both structurally and fluidly" connect the fluid distribution chamber and the fluid return chamber.
an excess volume area capable of operating at the accelerated pulsed rate, wherein the excess volume area is in fluid communication with the fluid return chamber providing a volume for storing a volume of a test system fluid when the test system fluid is under compression.		Excess volume area Fluid return chamber  The excess volume area is indicated with a red arrow. As discussed above, the device operates at an accelerated rate. Therefore, the excess volume area is "capable of operating at the accelerated pulsed rate." Moreover, as shown, test fluid is able to move from the fluid return chamber to the excess volume area. In other words, the two are "in fluid communication." This is confirmed by the specification of the '210 Patent, which discusses the flow of test fluid into the excess volume area from the fluid return chamber. '210 Patent col.10, l.66—col.11, l.22. When the test system fluid is under compression it flows through the valve into the fluid return chamber. A portion of this fluid is stored in the excess volume area as shown below:

		
9. The device of claim 1, wherein the excess volume area comprises a compliance chamber defining a cavity within the fluid return chamber.	"Compliance chamber" is a cavity or volume that functions to absorb some of the pressure in the system.	 As the image shows, the excess volume area is a cavity within the fluid return chamber. In the '210 Patent specification, it notes that this airspace is a "compliancy feature." '210 Patent col.7, ll.51-52. In other words, when the fluid is compressed, the airspace absorbs some of that pressure, working as a gas spring. '210 Patent col.11, ll.8-22,32-34. Therefore, the excess volume area comprises a compliance chamber.

26. The '224 Patent

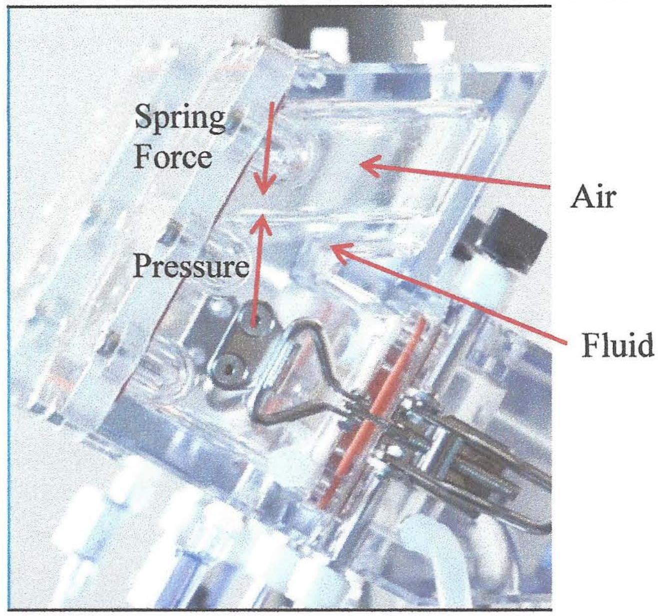
Claim Limitation	Claim Construction	Presence of Limitation in DuraPulse System
1. A method for operating an accelerated cyclic test system for evaluating a valved prosthetic device comprising		As discussed above, the DuraPulse is a device used for accelerated heart valve durability testing. Therefore, any method for operating the DuraPulse is a method for operating an accelerated cyclic test system for evaluating a valved prosthetic device.
driving a test system fluid cyclically above a normal physiological rate, at an accelerated pulsed rate of greater than 200 beats per minute within the test system;		The DuraPulse system has a linear motor that operates at between 15-30 Hz. http://www.tainstruments.com/wp-content/uploads/ElectroForce-Cardio-Test-Instruments.pdf at 13. When in operation the linear motor drives the test fluid. Mathematically, 15-30 Hz corresponds to a cyclical pulse rate of between 900-1800 bpm. I understand that the ISO 5850 requirements define "normal physiological rate" as between 30-200 beats per minute. Therefore, the DuraPulse device has a test system fluid cyclically above a normal physiological rate.
storing a volume of test system fluid in an excess volume area during a system driving stroke that opens the valved prosthetic device; and		

<table>
<tr><td></td><td></td><td>During the driving stroke, the DuraPulse system stores working fluid in an excess volume area shown in the image at the top of the left-hand chamber.

As described in the specification of the '210 Patent, as a bellows compresses the test fluid (i.e., during the drive stroke), fluid flows through the valve causing it to open, which causes some test fluid to then compress the air and thereby move into the previously occupied airspace (i.e., the excess volume area). '210 Patent col.11, ll.12-22.</td></tr>
<tr><td>releasing the stored volume of test system fluid during a return stroke that closes the valved prosthetic device.</td><td></td><td> The fluid from the excess volume area drains as fluid flows through return ports to the other side of the closed valve.

During the return stroke, the valved prosthetic device closes and the stored volume is released as the working fluid flows out of the second chamber through a return path in the ports surrounding the valve.

As described in the specification of the '210 Patent, as the bellows is drawn back (i.e., during a "return stroke"), fluid is released from the excess volume area causing an increase in the volume of the airspace. '210 Patent col.11, ll.23-31. This is shown in the</td></tr>
</table>

		video of the operation of the DuraPulse as well.
6. The method of claim 1, further comprising compressing a volume of a compressible gas with the volume of test system fluid to provide a spring force counter to and in response to a pressure on the test system fluid when the volume of test system fluid is stored in the excess volume area.		 When the return fluid chamber fills with test fluid, it compresses the air in the excess volume area providing for storage of additional fluid volume, while also providing a spring force that is counter to and in response to the pressure on the test fluid. Indeed, the specification of the '210 Patent specifically notes that the airspace "functions as a gas spring." '210 Patent col.11, l.34.

I declare under the penalty of perjury that the foregoing is true and correct.

Executed on 11/22, 2017 in LINO LAKES, MN.

Michael J. Girard

Michael J. Girard